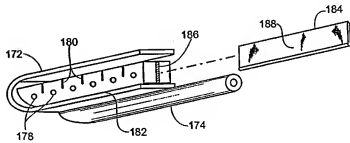


PRE-APPEAL BRIEF REQUEST FOR REVIEW

This request for review of the Final Office Action of July 29, 2009 is accompanied by a Notice of Appeal. Applicant respectfully submits that in rejecting all claims under 35 U.S.C. 103 as being unpatentable over U.S. Patent Publication No. 2003/0208209 (Gambale), the Final Office Action has made clear errors that merit this request for review.

The Claimed Invention

Claim 1 recites an apparatus for forming a lumen from within a hollow body organ. The apparatus includes a first opening in a first region for releasably adhering a first area of tissue and a second opening in a second region for releasably adhering a second area of tissue, the first and second openings being separated by a septum. The apparatus also includes a fastener housed within, and wherein the septum is "removable" from between the first and second openings to allow the fastener to be deployed such that the first area of tissue is secured to the second area of tissue via the fastener. This is depicted by the example shown in FIG. 9B (above) and discussed in the accompanying text of the specification at paragraphs 98 – 103.



The Gambale Reference

Gambale discloses a capsule with multiple suction ports for capturing multiple folds of tissue with a single device. The Abstract claims that the "improvement" reduces the number of intubations required during an endoscopic procedure. The Gambale reference refers to element 852 as the "capsule body surface," although the Office Action refers to it as the "septum" of Claim 1. Note also that a slot 894 between the two ports allows a fastener to attach the tissue folds without removing the portion of the capsule asserted by the Office Action to meet the septum requirement. That is, the Gambale capsule does not require removal of a septum to "allow the at least one fastener to be deployed" as required by Claim 1, having provided for a simple yet different mechanism for deploying a fastener without removing part of the capsule.

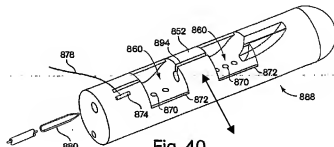


Fig. 40

The Rejection Of Claim 1

The Office Action relies only on the Gambale reference and the ordinary skill in the art to reject Claim 1. Specifically, the Office Action appears to argue that the structure between the ports **860** is a "septum" as recited in Claim 1, and further concludes that it would have been obvious to modify Gambale in order to have this structure be "removable," despite Gambale's statement that one benefit of the capsule is that it can be formed of a "single piece injection molded unit." Further, while the Examiner does not specify, it would appear that the septum would need to be moved transversely in the direction of the arrows shown on the drawing in order to carry out the purported benefits of the Examiner's proposed combination. How the structure could be made to move this way, and still carry out the objectives of Gambale, is not explained by the Examiner. Making the middle portion of the body "removable" would create numerous problems, not the least of which is the adverse effect of the device's ability to sustain vacuum in the two ports, since now the continuous adjoining surfaces would need to be discontinuous to allow for a sliding movement of a major portion of the capsule, leading to leaks, expensive seals, and other suction related problems. Moreover, since Gambale already devised a way to abrade the tissue **without** a removable septum, it is unclear why one of ordinary skill in the art would choose to modify Gambale's structure in order to: (1) make his capsule far more complicated; (2) eliminate the benefit of single piece injection molding; and (3) jeopardize the vacuum capabilities, only to purported achieve a result that the device already accomplishes without the modification. Applicant respectfully submits that this does not seem rational or obvious.

In response, the Final Office Action makes three arguments. First, the Office Action argues that "it *may* occur to one of ordinary skill in the art to make the septum removable in order to allow the user to change the abrasion means of the septum before applying the device to tissue." [O.A., p. 4 (emphasis added)] Presumably the Examiner is referring to Figures 41 and 42, suggesting that the portion of the capsule body between the two ports could be made into a removable component. This suggestion does not come from the prior art, and completely disregards the fact that the Gambale capsule is a single piece of injection molded material. To create a removable septum where none is taught is the height of hindsight reconstruction, particularly where it will serve no useful purpose and drastically complicate Gambale's single piece unit. Moreover, the standard for an obviousness rejection is not what one of ordinary skill

"may" have considered, but what the person of ordinary skill **would** have found obvious. See 35 U.S.C. §103:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole **would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.*
(Emphasis added)

By stating on the record that one of ordinary skill "may" have thought of the proposed modification, the Examiner has already conceded that the standard for obviousness has not been, can cannot be, met. Therefore, the rejection must be withdrawn.

The Office Action secondarily argues that it "**may**" be beneficial to have a removable septum to "selectively" abrade the tissue. Applicant is wholly unclear as to what this means, or how this could be carried out. However, the standard for obviousness is not what "may be beneficial," but rather what one of ordinary skill in the art would find "obvious." The Office Action cites to nothing in the prior art other than Gambale to establish its arguments, but one of ordinary skill in the art could not possibly envision the modifications proposed by the Office Action unless one's sole purpose was to invalidate Applicant's claims. There is no structure, teaching, or rationale for modifying the Gambale capsule to incorporate a removable septum, and the Office Action's reliance on what one "may" find beneficial cannot satisfy the Office's burden of establishing a *prima facie* case of obviousness.

Finally, the Office Action states that "it has also been held that constructing a formerly integral structure in various separable, removable elements involves only a routine skill in the art, and therefore it would have been an obvious modification to make the septum removable." [O.A., p. 4] First, the Office Action fails to support its assertion with an actual legal citation, so Applicant cannot address the purported authority on which the Examiner is relying upon. More importantly, the statement misses the point. Applicant is not claiming the patentable invention lies in how to make the septum movable, but rather the prior art does not suggest the desirability of modifying the single piece injection molded capsule of Gambale to have its entire middle portion move (presumably) transversely using some unspecified drive means in order to accomplish what the capsule already does without such modification. For the Office Action to

argue that the Applicant's invention is not patentable because integral components *can* be made separately wholly misses the mark.

In summary, Claim 1 calls for, *inter alia*, a removable septum. There is nothing in the prior art that fairly suggests removing a portion of the body of the Gambale one-piece capsule to meet this claim limitation. Not only is this unnecessary and would defeat the benefit of Gambale, but there is nothing that suggests much less teaches how this can be accomplished. Claim 1 also requires that the removal of the septum "allow" the fastener to be deployed, and the Office Action merely skips over this portion of the claim without demonstrating how this feature is met.

Claim 31 is similar. All claims are allowable based on this error. Because the Office Action has failed to properly establish with evidence of record a *prima facie* case of obviousness, the rejection must be withdrawn. Applicant respectfully requests reconsideration of the claims based on the remarks above, which establish clear error with the rejection of Claims 1 and 31.